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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/741,881	12/22/2000	Norman G. Anderson	2316-143	5632

6449 7590 03/25/2003

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EXAMINER
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PADMANABHAN, KARTIC *K*

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/741,881

Applicant(s)

ANDERSON, NORMAN G.

Examiner

Kartic Padmanabhan

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 and 19-27 is/are pending in the application.
- 4a) Of the above claim(s) 19-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-10 and 19-27 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15. 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election with traverse of Group I in Paper No. 14 is acknowledged. The traversal is on the ground(s) that a search for both groups would be coextensive and additional effort would not be required. This is not found persuasive because the record set forth in the previous restriction requirement clearly indicates that the delineated inventions are, in fact, patentably distinct, each from the other, and their different classification would necessitate additional searching.

The requirement is still deemed proper and is therefore made FINAL.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1 is rejected as vague and indefinite for the recitation of "capable" because it has been held that the recitation that an element is "capable of" performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

### *Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stocker (US Pat. 4,560,647). The reference teaches a method for the determination of antigens or antibodies in a fluid sample by incubation of particles, which have antigens of the surface, and antibodies. The antigen/antibody complex is introduced into a container having a conical shaped bottom, wherein the bottom of this container is coated with an immunoglobulin component directed against the antibodies. The determination of sediment (after centrifugation) is an indication of the amount of analyte present (Col. 2, lines 10-23). In addition, the antigen/antibody complex is freed from unbound immunoglobulin. This may be done by centrifuging the fluids containing the complex through a cushion containing a further liquid, wherein the density of the cushion is greater than that of the other fluid. It is therefore inherent that some sort of density gradient is created during this step. The method of the reference is especially suitable for the determination of viral antigens or viral antibodies (Col. 2, lines 29-32). The container of the reference may be a cuvette (Col. 2, lines 56-59). Since the bottom of the container is coated with binding agent, it is inherent that there are plural binding agents and that these binding agents are on different parts

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of the solid phase, as one binding agent cannot cover the entire bottom surface of the container. However, the reference does not teach the concentration or staining of particles, or the segmenting of microorganisms.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the method of Stocker to segment microorganisms and stain the particles at some time during the analysis. Since viral antigens or antiviral antibodies could be determined with the method of the reference, one could have easily used the virus particle itself with a reasonable expectation of success. In addition, it would have been obvious to stain the particles before visualization, as this would allow for more efficient and accurate measurement of the amount of analyte presence. Further, it would have been obvious to concentrate the particles for analysis prior to conducting the binding assay, as this step would allow for greater binding efficiency.

#### ***Response to Arguments***

8. Applicant's arguments filed 9/30/02 have been fully considered but are not persuasive to overcome Stocker.

9. Applicant's arguments that Stocker fails to teach the limitation of concentration of particles on a first phase in newly amended claim 1 is accurate, thereby necessitating the application of the reference under 35 USC 103 rather than 35 USC 102.

10. Applicant's arguments that there is no motivation to concentrate in Stocker due to the use of red blood cells is not convincing. RBCs are but one example of the particles of the Stocker reference, and a reference is in no way limited to its examples. Further, applicant's arguments that the examiner's proposed modification to render claims 7-8 and 10 obvious would not result

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in the claimed invention are not convincing. Although individual wells are indeed shallow, the reference contemplates the use of cuvettes, as well as microtiter plates.

***Conclusion***

Claims 1-10 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-5207 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan  
Patent Examiner  
Art Unit 1641

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March 24, 2003

  
LONG V. LE  
SUPERVISORY PATENT EXAMINER  
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03/24/03